

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC., and
BIOCON BIOLOGICS INC.

Defendants.

Civil Action No. 1:22-cv-00061-TSK

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION
TO CLOSE LIMITED PORTIONS OF TRIAL PROCEEDINGS**

Defendants Mylan Pharmaceuticals Inc. (“Mylan”) and Biocon Biologics Inc. (“Biocon”) (collectively, “Defendants”) submit this memorandum of law in support of their motion to close limited portions of the trial proceedings to the public, and to seal corresponding exhibits and portions of the trial transcript. Defendants specifically seek to exclude the public from the limited portions of the trial in which there is disclosure of certain highly confidential and competitively sensitive details of Defendants’ proposed Yesafili product. Defendants seek to close only those portions of the trial that involve disclosure or discussion of (1) both the specific excipients or other constituents of the product and the relative proportions and/or the specific amounts of each such constituent or excipient; (2) portions of Biocon’s Biologics License Application (“BLA”) containing other competitively sensitive research and development and/or product details; and (3) specific clinical trial data beyond that in the label, including individual patient data submitted to the Food and Drug Administration (“FDA”). Mylan and Biocon have maintained in confidence the relevant information, and the information is either competitively sensitive and proprietary, or will not become available to the public until licensure of the BLA by the FDA. Public disclosure

of technical details of the Yesafili product would allow competitors a substantial advantage in creating a competing product and obtaining FDA approval of that product, which would greatly prejudice Biocon, as the current holder of the BLA for Yesafili. As shown below, the competitive harm that would arise from public disclosure, and very limited scope of restrictions on disclosure, justify granting Defendants' motion.

The Fourth Circuit has recognized that disclosure of competitively sensitive information is a proper basis for limited closure of civil trial proceedings. *Woven Elecs. Corp. v. Advance Grp., Inc.*, Nos. 89–1580, 89–1588, 1991 WL 54118 (4th Cir. 1991). In *Woven Electronics*, the Fourth Circuit held that the trial court had erred in failing to close portions of a trial involving the alleged theft of trade secrets. *Id.* at *6. The Fourth Circuit held that there is a presumption that trial proceedings are open, but also recognized that the right was “not unlimited” and that “one exception to the public’s right of access is where such access to judicial records could provide a ‘source[] of business information that might harm a litigant’s competitive standing.’” *Id.* (quoting *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 598 (1978)). The court held that trade secrets could constitute a compelling interest that would justify an exception to the general First Amendment right of access to judicial proceedings, noting that “[o]ther courts have specifically recognized an exception to the public’s right of access when a case involves trade secrets.” *Id.* (citing *Valley Broadcasting v. United States District Court*, 798 F.2d 1289, 1294 (9th Cir. 1986); *In re Iowa Freedom of Information Council*, 724 F.2d 658 (8th Cir. 1983); *Brown & Williamson Tobacco Co. v. FTC*, 710 F.2d 1165, 1180 (6th Cir. 1983)).

In a related context, the Federal Circuit reversed a district court order refusing to seal documents related to pre-trial and post-trial motions in patent litigation. *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1226-28 (Fed. Cir. 2013). Applying the law of the Ninth Circuit, the

Federal Circuit regarded the documents as likely subject to sealing on the showing of “good cause,” but the court found that the more stringent “compelling reasons” standard had been met. *Id.* at 1223. The court specifically found that Apple and Samsung were entitled to protection of product-specific “profit, cost and margin data” because they would be put at a competitive disadvantage if the information were disclosed to suppliers or competitors. *Id.* at 1225. The court considered the countervailing public interest in the documents and found that the highly detailed information was not necessary to the public’s understanding of the case. *Id.* The same is true with respect to the specifics of the Yesafili product. Although the existence of some components may be pertinent to the infringement or other legal issues, the exact composition of the product and the relative amounts of its various components will not be necessary for the public to understand any ruling of the court or outcome of the trial.

Other courts have recognized the propriety of protecting competitively sensitive information by closing judicial proceedings or sealing portions of such transcripts. In *Standard & Poor's Corp. Inc. v. Commodity Exch., Inc.*, 541 F. Supp. 1273 (S.D.N.Y. 1982), the court held that the courtroom had properly been closed to the press and public for a portion of a preliminary injunction hearing and denied the motion of a news organization to unseal the portion of the transcript for the closed portion of the five-day proceeding. The court held that the information discussed at the closed proceeding related to internal details of the creation of the Standard and Poor’s stock index, that constituted trade secrets of the company and that disclosure would cause irreparable harm. *Id.* at 1277. Given the limited scope of the closure (less than one hour) compared to the full five-day proceeding, the least restrictive alternative had been adopted by the court. *Id.*

The interests of a party in its proprietary technology was also found to outweigh the public interest in open proceedings in *Wood v. Robert Bosch Tool Corp.*, No. 4:13-CV-01888 PLC, 2016

WL 7013034 (E.D. Mo. Nov. 30, 2016). There, the court had granted a motion to close the courtroom for limited portions of a trial over injuries caused by a table saw; the closed portions related to development of proprietary protective features of the defendant's table saw. *Id.* at *3. After redacted versions of the relevant transcripts were publicly filed, the court granted a motion to maintain the redacted portions under seal. *Id.* at *8. The Court found that the interests of the defendant in development of its proprietary technology outweighed the public interest in the sealed portions of the transcript. *Id.*

Here, Defendants will seek closure of only limited portions of testimony, dealing with a narrow issue that is of great competitive significance to Defendants, but is of no significance to the public's understanding of the case or the Court's ruling. At the conclusion of the case, Defendants will provide a proposed redacted version of any relevant transcript volumes, for public filing, to further narrow the scope of information that is not publicly available.

For these reasons, and others appearing of record, Defendants request that the Court close the courtroom to the general public, and to all persons other than court personnel and representatives of the parties subject to the court's protective order, during those limited portions of trial proceedings discussing or disclosing (1) both the specific excipients or other constituents of the Yesafili product and the relative proportions and/or the specific amounts of each such constituent or excipient; (2) portions of Biocon's Biologics License Application ("BLA") containing other competitively sensitive research and development and/or product details; and (3) specific clinical trial data beyond that in the label, including individual patient data submitted to the Food and Drug Administration ("FDA") Defendants further move the Court to seal those exhibits and those portions of the trial transcript disclosing such information.

Respectfully submitted this 12th day of June, 2023.

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CERTIFICATE OF SERVICE

I certify that on the 12th day of June 2023, the foregoing “Defendants’ Memorandum of Law In Support of Motion to Close Limited Portions of Trial Proceedings” was served via hand-delivery and filed thereafter with the Court’s CM/ECF system, which will send a copy of the same to all counsel of record.

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